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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

October 24, 1997

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 7

Thomas L. Gould
President
G.H. Medical, Inc.
2010 East Hennepin Avenue, #211A
Minneapolis, Minnesota 55413

Dear Mr. Gould:

We are writing to you because on September 26 and October 1, 2, and 10, 1997, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving ambulatory blood pressure monitoring systems that are made and marketed by your firm.

Under United States Federal law, the Federal Food, Drug and Cosmetic Act (the Act), a product is considered to be a medical device if it is used to diagnose or treat a medical condition or is intended to affect the structure or function of the body. Ambulatory blood pressure monitoring systems are medical devices as defined by Section 201(h) of the Act.

The law requires that manufacturers of medical devices adhere to current Good Manufacturing Practice (GMP) regulations for Medical Devices as specified in Title 21, Code of Federal Regulations (CFR), Part 820, in the methods used in, facilities or controls used for manufacturing, packing, storage of installation of medical devices.

Our inspection found your products violate the law because of:

1. Failure to establish and maintain procedures for implementing corrective and preventive action including requirements for investigating the cause of nonconformities relating to product processes and the quality system, and for identifying the action(s) needed to correct and prevent recurrence of non-conforming product and other quality problems (21 CFR 820.100). Additionally the firm fails to document the evaluation and investigation into product that does not conform to specified requirements [21 CFR 820.90(a)]. For example:

   a. G.H. Medical has not identified a long-term fix for failures in the field; and

   b. Complaint #CS0001-12997 does not state if and what corrective action was taken.

2. Failure to establish and maintain procedures to control all documents including those in the device master record (DMR) and work instructions [21 CFR 820.40(a)]. For example, the procedure for final testing of the models 9232 and 9241 is not signed and dated as having been reviewed and approved. The parameters used in the final testing of these models are not specified.

3. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specifications (21 CFR 820.50) and to evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements [21 CFR 820.50(1)(1)], in that G.H. Medical has not audited their contracting manufacturer and has no procedures for evaluating and selecting potential suppliers, contractors, or consultants.

4. Failure to document all complaints in sufficient detail to include all the requirements of 21 CFR 820.198(e). For example, the complaint form dated 4/24/97 does not include any device identification(s) and control

numbers used, the nature of the complaint(s), and the name, address, and phone number of the complainant. Additionally, the firm has not recorded all of the complaints regarding "trend graph" problems as required by 21 CFR 820.198(a).

In legal terms the products are adulterated under Section 501(h) of the Act.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

The specific violations noted in this letter and in the FDA-483 issued at the close-out of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions. Your corrective actions should extend to all applicable products and product lines.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. As president, the most responsible individual at G.H. Medical, Inc., it is ultimately your responsibility to ensure that devices manufactured at your facility in Minneapolis, MN, are in compliance with each requirement of the Act and regulations.

It is necessary for you to take action on this matter now. Please let this office know in writing within 15 working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Compliance Officer Howard E. Manresa at the address indicated on the letterhead.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of current Good Manufacturing Practices for your devices and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-800-638-2041 or through the Internet at http://www.fda.gov.

If you have more specific questions about how FDA marketing requirements affect your particular device or about the content of this letter, please feel free to contact Mr. Manresa at (612) 334-4100 ext. 156.

Sincerely,

James A. Rahto
Director
Minneapolis District

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